IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Doddabele L. Madhavi, *et al.*
Serial No.	:	10/748,096
Filed:	:	December 30, 2003
For:	:	A Highly Bioavailable Coenzyme Q-10/Cyclodextrin Complex
TC/AU	:	1623
Examiner	:	Matthew L. Fedowitz
Attorney Docket No.	:	BIO 2-013

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INFORMATION DISCLOSURE STATEMENT

Sir:

This Information Disclosure Statement is filed in conformity with 37 C.F.R. §§ 1.56, 1.97 and 1.98. Accordingly, copies of the art cited herein are provided:

Document	Date	Name
U.S. Patent Application Publication No. 2003/0012774 A1	2003	Moldenhauser *et al.*
U. S. Patent No. 6,461,593	2002	Hanioka *et al.*
DE10139851 (WO203026603)	2003	Kaden Waltraud, *et al.*
EP11174109	2002	Jens Nielsen, *et al.*
JP56109590	1981	Yonezawa Yusua, *et al.*
"Accumulation and retention of micellar β-carotene and lutein by Caco-2 human intestinal cells", *J. Nutr. Biochem.*, 10: 573-581, 1999.	1999	Garrett, D.A., Failla, M.L., Sarama, R.J., and Craft, N.
"Inclusion complexation of CoQ-10 with cyclodextrins", *Acta Pol. Pharm.*, 52:379-386, 1995	1995	Lutka, A. and Pawlaczyk, J.
"Investigation of inclusion complexes of CoQ-10 with γ-cyclodextrin and methyl-β-cyclodextrin. Part I. Comparison of complexation methods in the solution state", *Acta Pol. Pharm.*, 53: 193-196, 1996a.	1996	Lutką, A. and Pawlaczyk, J.,
"Investigation of inclusion complexes of CoQ-10 with γ-cyclodextrin and methyl-β-cyclodextrin. Part II. The influence of	1996	Lutka, A. and Pawlaczyk, J

complexation temperature (heating method) on CoQ-10 solubility", *Acta Pol. Pharm.*, 53: 197-201, 1996b.		
"Investigation of inclusion complexes of CoQ-10 with γ-cyclodextrin and methyl-β-cyclodextrin. Part III. The influence of cyclodextrins on CoQ-10 stability", *Acta Pol. Pharm.*, 54: 279-285, 1997	1997	Lutka, A. and Pawlaczyk, J.
"A moderate interaction of maltosyl-alpha-cyclodextrin with Caco2 cells in comparison with the parent cyclodextrin", *Biol. Pharm. Bull.*, 24: 395-402, 2001.	2001	Ono. N., Arima, H., Hirayama, F., and Uekema, K.
"Uptake and passage of beta lactoglobulin, palmitic acid and retinal across the Caco-2 monolayer", *Biochim. Biophys. Acta.*, 1236: 149-154, 1995.	1995	Puyol, P., Perez, M.D., Sanchez, L., Ena, J.M., and Calco, M.
"Cyclodexrins as mucosal absorption promoters of insulin. II. Effects of beta-cyclodextrin derivatives on alpha-chymotryptic degradation and enteral absorption of insulin in rats", *Pharm Res.*, 11: 1174-9, 1994.	1994	Shao, Z., Li, Y., Chermak, T., and Mitra, A.K.
"Intestinal safety of water soluble beta-cyclodextrins in pediatric oral solutions of spironolactone: effects on human epithelial Caco-2 cells", *J. Pharm. Pharmacol.*, 49: 43-8, 1997.	1997	Totterman, A.M., Schipper, N.G., Thompson, D.O., and Mannermaa, J.P.
"Vitamin E uptake by human intestinal cells during lipolysis in vitro", *Gastroenterology*, 98: 96-103, 1990.	1990	Traber, M.G., Goldberg, I., Davidson, E., Lagamy, N., and Kayden, H.J.
"Transepithelial transport of putrescine across monolayers of the human intestinal epithelial cell line, Caco2", *World J. Gastroenterol.*, 7: 193-197, 2001.	2001	Turchanowa, M.V., Stein, L., and Caspary, W.F.
"Improvement of dissolution and absorption characteristics of ubidecarenone by dimethyl-β-cyclodextrin complexation", *Acta Pharm. Nord.*, 1: 99-104, 1989.	1989	Ueno, M., Ijitsu. T., Horiuchi, Y., Hirayama, F., Uekama, K.
"The effect of parenterally administered cyclodextrins on cholesterol levels in the rat", *Pharm. Res.*, 8: 9-16, 1991	1991	Frijlink, H.W., Eissens, A.C., Hefting, N.R., Poelstra, K., Lerk, C.F., and Meijer, D.K.
"Studies on the inclusion compound between β-cyclodextrin and cholesterol", In D. Duchene (Ed), 5th *International Symposium on Cyclodextrins*, 1990, pp 299-302, Editions de Sante, Paris	1990	Fridrich, R., Mehnert, W., Fromming, K.H.

"Cyclodextrins as carriers of cholesterol and fatty acids in cultivation of mycoplasmas", *Appl. Envr. Microbiol.*, 59: 547-551, 1993).	1993	Greenberg-Ofrath, N., Terespolosky, Y., Kahane, I., and Bar, R.
"Comparison of impact of the different hydrophilic carriers on the properties of piperazine-containing drug", *Eur. J. Pharm. Biopharm.*, 51: 221-225, 2001.	2001	Ahmed, M.O.
"Comparative study on inclusion complexation of maltosyl-beta-cyclodextrin, heptakis(2,6-di-O-methyl)-beta-cyclodextrin and beta-cyclodextrin with fucosterol in aqueous and solid state", J. *Pharm. Pharmacol.*, 45: 1028-32, 1993	1993	Acarturk, F., Imai, T., Saito, H., Ishikawa, M., and Otagiri, M.
"Effect of inclusion complexation with cyclodextrins on photostability of nifedipine in solid state", *Int. J. Pharm.*, 243: 107-17, 2002	2002	Bayomi, M.A., Abanumay, K.A., and Al-Angary, A.A.
"Enhancement of dissolution and oral bioavailabilty of gliquidone with hydroxypropyl-beta-cyclodextrin", *Pharmacia*, 2003: 58 (11): 807-10	2003	Sridavi, *et al.*,
Physiocochemcial characterization and in vitro dissolution behavior of nicardipine hydrochloride inclusion compounds". *Eur J Pharm Sci.* 2002 Feb; 15(1): 79-88	2002	Fernandes, *et al.*
Effect of the hydrophobic nature of triacetyl-β-cyclodextrin on the complexation with nicardipine hydrochloride: physicochemical and dissolution properties of the kneaded and spray-dried complex", *Chem Pharm Bull* (Tokyo). 2002 Dec; 50 (12): 1597-602	2002	Fernandes, *et al.*
"Effects of the host cavity size and preparation method on the physicochemical properties of ibuproxam-cyclodextrin systems", *Drug Dev Ind Pharm.* 1999 Mar:25(3) :279-87	1999	Mura, *et al.*
"Preparation and characterization of albendazole beta-cyclodexrin complexes", *Drug Dev Ind Pharm.* 1999 Dec; 25(12) :12418	1999	Castillo, *et al.*
"Influence of the preparation method on the physicochemical properties of ketoprofen-cyclodextrin binary systems", *Int J Pharm.* 1999 Mar 1; 179(1): 117-28	1999	Muza, *et al.*
"Influence of the preparation method on the physicochemical properties of binary systems of econazole with cyclodextrins", *Int J Pharm.* 1999 Dec 20; 193(1): 85-95	1999	Mura, *et al.*

"Review-Cyclodextrins in topical drug formulations: Theory and Practice", *Int. J. Pharm*, 225: 15-30, 2001	2001	Loftsson, T. and Masson, M.

REMARKS

It respectfully is submitted that none of the foregoing art, alone or in combination, shows or proposes the present invention. Accordingly, favorable action on the application respectfully is requested.

Respectfully submitted,

Date: 20 Jan. 2005

Jerry K. Mueller, Jr.
Reg. No. 27,576
MUELLER AND SMITH, L.P.A.
Mueller-Smith Building
7700 Rivers Edge Drive
Columbus, Ohio 43235-1355
Tel.: 614.436.0600
Fax: 614.436.0057
email: *smueller@muellersmith.com*

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Sheet 1 of 4

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Application Number	10/748,096
Filing Date	December 30, 2003
First Named Inventor	Doddabele L. Madhavi
Art Unit	1623
Examiner Name	Matthew L. Fedowitz
Attorney Docket Number	BIO 2-013

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 2003/0012774A1	01-16-2003	Moldenhauer, et al.	
		US- 6,461,593	10-08-2002	Hanioka, et al.	
		US- DE10139851	03-13-2003	Waltraud, et al.	
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Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
		EP1174109	01-23-2003	Nielsen, et al.		
		JP56109590	08-31-1981	Yonezawa, et al		

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	1.	"Accumulation and retention of micellar b-carotene and lutein by Caco-2 human intestinal cells", J. Nutr. Biochem., 10: 573-581, 1999.	
	2.	"Inclusion complexation of CoQ-10 with cyclodextrins", Acta Pol. Pharm., 52:379-386, 1995	
	3.	"Investigation of inclusion complexes of CoQ-10 with g-cyclodextrin and methyl-b-cyclodextrin. Part I. Comparison of complexation methods in the solution state", Acta Pol. Pharm., 53: 193-196, 1996a.	
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	9.	"Intestinal safety of water soluble beta-cyclodextrins in pediatric oral solutions of spironolactone: effects on human epithelial Caco-2 cells", J. Pharm. Pharmacol., 49: 43-8, 1997.	
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	18	"Effect of inclusion complexation with cyclodextrins on photostability of nifedipine in solid state", Int. J. Pharm., 243: 107-17, 2002	
	19	"Enhancement of dissolution and oral bioavailabilty of gliquidone with hydroxypropyl-beta-cyclodextrin", Pharmacia, 2003: 58 (11): 807-10	
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	22	"Preparation and characterization of albendazole beta-cyclodexrin complexes", Drug Dev Ind Pharm. 1999 Dec; 25(12) :12418	
	23	"Influence of the preparation method on the physicochemical properties of ketoprofen-cyclodextrin binary systems", Int J Pharm. 1999 Mar 1; 179(1): 117-28	
	24	"Influence of the preparation method on the physicochemical properties of binary systems of econazole with cyclodextrins", Int J Pharm. 1999 Dec 20; 193(1): 85-95	
	25	"Review-Cyclodextrins in topical drug formulations: Theory and Practice", Int. J. Pharm, 225: 15-30, 2001	

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